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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Application of: Dr. Donald G. Russell)

) Group Art Unit: 2882

on)

AN INTERMEDIATE
DENSITY MARKER AND A
METHOD USING SUCH A
MARKER FOR
RADIOGRAPHIC
EXAMINATION

) Examiner: C. E. Church

Application Serial No. 09/372,835)

Filed on August 12, 1999)

) (Docket No. 054360.0005)

Dated at Hartford, Connecticut, this 5th day of August 2002.

Commissioner for Patents
Washington, DC 20231

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I. INTRODUCTION

The Examiner's withdrawal of the rejections based on the Zinreich et al (U.S. Patent No. 5,469,847) at paragraph (6) of the Examiner's Answer is gratefully acknowledged. Accordingly, the only remaining issue on appeal is the rejection of claims 20-61 under 35 U.S.C. § 103 as being unpatentable over DeSena (U.S. Patent No. 5,193,106). It is respectfully submitted that DeSena is no more material to the presently claimed invention than is Zinreich et al., and therefore the remaining rejection should be withdrawn for the same reasons that the rejection based on Zinreich et al. was withdrawn.

II. ARGUMENT

A. **DeSena's Teachings Are Limited To Radiopaque Markers That Closely Encircle Cutaneous Landmarks For Podiatric Evaluations.**

DeSena wholly fails to teach or suggest providing a marker made of a partially radiopaque, partially radiolucent material, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail of the tissue clearly visible through the radiographic shadow of the marker, as recited in the independent claims.

Rather, DeSena's teachings are exclusively directed to *radiopaque* markers for examining problematic deep structures of the foot that are denoted by cutaneous landmarks. DeSena states under his "Field of the Invention": "the invention relates to a marker device to be used in podiatric evaluations, wherein the marker device encompasses and defines the area under visual examination in such a way that this area can later be correlated with a radio-photograph." (Col. 1, ll. 8-13). In addition, the preamble of each of DeSena's claims states: "A marker device to be used in the x-ray

examination of problematic deep structures of the foot, wherein said problematic deep structures of the foot are denoted by cutaneous landmarks" (Col. 5, l. 52 - col. 6, l. 2; and col. 6, ll. 24-27).

In his "Background Of The Invention", DeSena explains in detail the problems encountered in the prior art methods of podiatric evaluation, and the markers used in such methods, in order to set the framework establishing the need for his invention. In particular, DeSena explains the unique problems associated with podiatric radiographic examinations of cutaneous landmarks. DeSena states that the prior art markers were either too large and/or not properly shaped for imaging podiatric cutaneous landmarks. As a result, DeSena explains that the prior art radiopaque markers would overlies and thus obscure the small region of interest, or would be too large to be placed close enough to the cutaneous landmark to be effective. For example, DeSena states:

A major shortcoming of the Duska [U.S. Patent No. 4,506,676] technique is that it [sic] tape only extends up to, and does not surround, the area of interest. Its usefulness is thus limited to the evaluation of large bones, such as the bones of the legs and arms; in the examination of small bones, such as those of the feet, the Duska marker does not adequately focus attention on the critical area. This is primarily due to the size of the Duska marker; it is simply too large to place close to the cutaneous landmark without obscuring the subcutaneous problem. Finally, *for fine work, such as in the examination of small bones of the toes, it is useful to completely delineate the cutaneous area in question, preferably by encircling it rather than pointing at it.* [Col. 1, ll. 55-68, emphasis added].

* * *

[T]he Williams marker [U.S. Patent No. 4,860,331] provides reference lines only. *These lines may obscure rather than encompass an area of interest as small as individual bones of the toes.* The Williams marker may be effective in indexing cross-sectional scans of the entire body, but it would hinder podiatric evaluations of much smaller areas of interest. [Col. 2, ll. 10-16, emphasis added].

* * *

Podiatrists are involved primarily in the evaluation of the small bones of the feet and are frequently concerned with isolating for examination very small subcutaneous areas based upon cutaneous landmarks which often exist on irregular surfaces in hard-to-reach locations. * * * An x-ray technique involving the use of a set of readily dispensable markers of various sizes and shapes *which can encompass the area of interest* would therefore increase the diagnostic efficiency and effectiveness of the podiatrist. [Col. 2, ll. 34-39 and ll. 53-57, emphasis added].

In order to overcome these stated problems in the prior art, DeSena's invention is directed to a radiopaque marker designed specifically for examination of problematic deep structures of the foot denoted by cutaneous landmarks. Every disclosed embodiment of DeSena's marker device comprises a *radiopaque* material that is affixed to an adhesive-backed tape and is formed into a shape "such that it *completely surrounds* a cutaneous landmark in a surrounding shape of an internal size comparable to that of cutaneous landmarks of podiatric pathologies". (Col. 6, ll. 8-13, emphasis added). Thus, DeSena's clear teaching is to form the marker of a radiopaque material that (1) is of a size comparable to that of cutaneous landmarks of podiatric pathologies, and (2) is shaped to closely surround or encircle such landmarks. As shown, for example, in FIG. 2 of DeSena, each radiopaque marker 3 is in the form of sharp, solid lines that are dimensioned to tightly surround or encircle cutaneous landmarks of podiatric pathologies. (See, e.g., DeSena's claim 6, which states "each of said circles has an inner diameter of a dimension sufficient to completely surround cutaneous landmarks of podiatric pathologies") (Col. 6, ll. 36-38).

B. DeSena Teaches Only Radiopaque Markers, And Makes No Teaching Or Suggestion Of Partially Radiopaque, Partially Radiolucent Markers That Show Underlying Anatomical Detail Through The Shadow Of The Marker.

Contrary to the Examiner's assertion, DeSena does not in any way describe his markers as being partially radiopaque and partially radiolucent such that anatomical

detail of the tissue is clearly visible through the radiographic shadow of the marker, as recited in Applicant's independent claims. Rather, DeSena repeatedly and consistently describes his markers as "radiopaque". In the Abstract, DeSena describes his marker device as follows:

A device for marking cutaneous landmarks . . . that comprises affixing a *radiopaque* material to an adhesive tape and placing the *radiopaque* material over a cutaneous landmark on a patient's foot and then x-raying the highlighted area. The *radiopaque* material is formed into any of a variety of shapes, such as a circle, triangle or square, so as to provide a marker that completely encompasses the cutaneous landmark. [Abstract at ll. 1-10, emphasis added].

Moreover, in the "Summary Of The Invention" and the "Preferred Embodiment Of The Invention", DeSena describes his marker as "radiopaque" on at least eight occasions. Similarly, in the claims, DeSena describes his marker as being "radiopaque" on at least seven occasions. Nowhere does DeSena describe, or even suggest that his marker is partially radiopaque and partially radiolucent such that anatomical detail of the tissue is clearly visible through the radiographic shadow of the marker, as recited in Applicant's independent claims. Indeed, DeSena makes no mention whatsoever of radiolucency.

Moreover, consistent with DeSena's statements in the specification that his markers are radiopaque, the radiographic images reflected in each of FIGS. 5-9B of DeSena's patent illustrate that each of his markers form on a radiograph opaque or solid lines, without any anatomical detail of the underlying tissue visible through the radiographic shadow of the marker, as in the presently claimed invention.

The fact that DeSena's markers are radiopaque and do not meet the terms of the presently claimed invention is further borne out by DeSena's summary of his invention,

wherein he states: "The novelty and utility of the present invention resides in its ability to mark areas of interest with markers that are large enough to *encompass* the region of interest, but small enough not to obscure the subcutaneous problem" (Col. 3, ll. 63-67, emphasis in original).

If DeSena's marker were truly partially radiopaque and partially radiolucent such that anatomical detail of the tissue would be clearly visible through the radiographic shadow of the marker, as recited in Applicant's claims, then DeSena would not be concerned with making the marker "large enough to *encompass* the region of interest, but small enough not to obscure the subcutaneous problem", as stated above. Id. Rather, it is axiomatic that DeSena's markers are radiopaque, and therefore must be shaped and dimensioned as taught by DeSena to tightly surround the cutaneous landmark and thereby avoid obscuring the subcutaneous problem.

DeSena's markers give rise to the very problem overcome by Applicant's claimed invention. In stark contrast to DeSena's radiopaque markers, Applicant's markers are partially radiopaque and partially radiolucent such that anatomical detail of the tissue is clearly visible through the radiographic shadow of the marker, as recited in the independent claims. As a result, Applicant's invention obviates the need to be concerned with the marker shapes and dimensions as taught by DeSena in order to avoid obscuring subcutaneous problems. Rather, any subcutaneous problems in the anatomical detail of the tissue would be clearly visible through the shadow of Applicant's claimed markers. Accordingly, DeSena shows no recognition of the advantages of Applicant's invention, much less any teaching of the structural features and method steps that give rise to those advantages, as recited in Applicant's claims.

C. The Examiner's Characterizations Of DeSena Are Unsupported And Incorrect.

Contrary to the statement at page 5 of the Examiner's Answer, DeSena does not provide any instruction to make the thickness or absorption of his marker "just enough to make the marker visible in the image but not to obscure details should it inadvertently be placed over a vital region beneath the skin". It is respectfully noted that the Examiner's Answer conspicuously fails to provide any quotation or citation to DeSena to support this assertion because such support does not exist. In addition, the citations at page 6 of the Examiner's Answer to lines 24-32 of column 1 and lines 62-64 of column 4 of DeSena do not even remotely "emphasize DeSena's desire that the marker not be so thick as to hide vital information," as asserted by the Examiner. (Examiner's Answer at 6). The statements made at lines 24-32 of column 1 of DeSena do not say anything about the thickness of the marker or otherwise support in any way the Examiner's conclusory statement.

Similarly, the Examiner's citation to column 4, lines 62-64, particularly when read in context of DeSena's entire disclosure, indicates that the lines formed by the radiopaque material must be sufficiently thick to highlight the area of interest with clarity. The word "thickness" singled out by the Examiner clearly refers to a line thickness (or width) sufficient to form distinct, solid (or opaque) lines encompassing the cutaneous landmark on the radiograph, as shown in FIGS. 5-9B, in order to highlight this area of interest. This statement is entirely consistent with, and in no way changes DeSena's clear teaching that the material form sufficiently thick radiopaque lines to highlight the encircled area of interest. Clearly, the Examiner is impermissibly applying hindsight reconstruction when he attempts to read into this statement a teaching to make the marker partially radiopaque

and partially radiolucent such that anatomical detail of the tissue is clearly visible through the radiographic shadow of the marker, as recited in Applicant's claims.

DeSena's only teaching to avoid obscuring a subcutaneous problem is to make the radiopaque marker "large enough to *encompass* the region of interest, but small enough not to obscure the subcutaneous problem" (Col. 3, ll. 64-67, emphasis in original). DeSena does not teach or suggest in any way adjusting the marker material, or the thickness or density of the marker material, to enable anatomical detail of the tissue to be clearly visible through the radiographic shadow of the marker, as recited in Applicant's claims.

The statement at page 6 of the Examiner's Answer that "DeSena does not imply that aluminum blocks all radiation . . . but that it is somewhat absorbent" also is entirely unsupported. As set forth above, DeSena repeatedly and consistently defines his markers as "radiopaque" and nowhere does DeSena state or even imply that his markers be only "somewhat absorbent". Moreover, the fact that both DeSena's marker and Applicant's marker may be made of aluminum has no bearing on the issue of obviousness. As indicated above, DeSena's entire teaching is directed to a marker device for podiatric evaluations. It is well known that x-ray examination of extremities, such as the foot where DeSena's marker is employed, involve relatively low energy x-ray sources (i.e., relatively low kVs). DeSena's aluminum markers are radiopaque at such energy levels as consistently stated and illustrated throughout DeSena's specification and drawings.

At page 6 of his Answer, the Examiner states: "Contrary to appellant's assertion, the rejection does not suggest modifying the DeSena marker but rather that the DeSena marker is, in fact, the same as is recited in claim 20." First, this statement is plainly

inconsistent with the Examiner's official rejection stated at page 3 of the Answer, which states: "It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the thickness or % attenuation of the DeSena markers to provide the desired opacity under the specified parameters." Clearly, the Examiner cannot assert on the one hand that the thickness or % attenuation of DeSena's marker must be modified to arrive at the claimed invention, and then assert on the other hand that DeSena's marker is the same as the marker recited in Applicant's claims. These inconsistencies render the Examiner's position nonsensical.

Moreover, if the Examiner truly believes that DeSena's marker is the same as the marker recited in Applicant's claim, then the claims should have been rejected as being anticipated under 35 U.S.C. § 102(b). Since the Examiner has maintained his rejection under 35 U.S.C. § 103, it must be assumed that his statement at page 6 of his Answer that DeSena's marker is the same as the claimed marker was made in error.

D. The Significant Evidence Of Commercial Success Must Be Considered, And Further Dictates A Reversal Of The Outstanding Rejection.

The Examiner cannot avoid his obligation to consider the significant evidence of commercial success in this application by incorrectly asserting that only one of Applicant's claim limitations is missing from DeSena's patent. In particular, the Examiner states at page 6 of his Answer that "the only limitation lacking in the DeSena disclosure is the specific statement that the marker must be less than 0.4 inches thick". This statement is not correct. With respect to independent claim 36 (or independent claims 20 or 59), DeSena does not in any way teach or suggest at least the following claim limitations:

providing a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both

project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in tissue having the predetermined tissue density when the marker and the tissue are exposed to the predetermined level of x-ray radiation during radiographic examination, said providing step including selecting the density and thickness of the marker based on the predetermined tissue density and the predetermined energy level of the radiation provided to absorb from about 2% to about 75% of the incident radiation;

positioning the marker between the source of x-ray radiation and the tissue having the predetermined tissue density; and

exposing the marker and the tissue to the x-ray radiation at the predetermined energy level, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

Similarly, with respect to independent claim 55 (or independent claim 46),

DeSena does not in any way teach or suggest a marker for mammographic or other radiographic examination comprising at least the following claim limitations:

a first outer surface for contacting a patient's breast tissue; a second outer surface located on an opposite side of the marker relative to the first outer surface; and means located between the first and second outer surfaces for generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

The Examiner's statement at page 7 of the Action that "any commercial success may stem from marketing or other practices and [sic] totally unrelated to patentability" is improper in this case. As made clear in Applicant's main brief, Beekley's commercial products constitute the invention disclosed and claimed in this application (as opposed, for example, to being only a component of the commercially successful device), and therefore this in and of itself establishes a prima facie nexus between the commercial success and the merits of the patented invention. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988), cert. denied, 488 U.S. 956 (1988). The

Examiner has failed to introduce any evidence or cogent reasoning to rebut this nexus. Accordingly, Applicant's evidence of commercial success must be considered and further dictates a reversal of the Examiner's rejection in view of DeSena.

E. DeSena's Marker Is Not The "Same As" Applicant's Claimed Invention.

The Examiner's argument at page 7 of his Answer that "[t]he 'obviousness' issue here is not obviousness to modify a prior art device . . . but rather obviousness that the prior art device is the same as the device being claimed", is confusing and seemingly nonsensical. If the Examiner is asserting that the marker device disclosed in DeSena is the same as the device recited in Applicant's claims, then his rejection should have been made under 35 U.S.C. § 102(b), not 35 U.S.C. § 103. However, since the Examiner has maintained his rejection under § 103, and states in that rejection that it would have been obvious to modify DeSena to arrive at the claimed invention, the Examiner's statement made at page 7 of his Answer must be an error.

In addition, if the Examiner is indirectly arguing inherency, any such basis for rejection also must fail. An inherency rejection requires the Examiner to establish that "the prior art necessarily functions in accordance with, or includes, the claimed limitations." Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the prior art." Ex Parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (reversing a patent examiner's inherency rejection) (emphasis in original).

The Examiner has failed to provide a reasonable basis in fact and/or cogent technical reasoning to show that a marker that is partially radiopaque and partially radiolucent such that anatomical detail of the tissue is clearly visible through the radiographic shadow of the marker, as recited in the independent claims, *necessarily* flows from the teachings of DeSena. To the contrary, as set forth above, DeSena's marker is radiopaque and is designed to form on a radiograph distinct, opaque or solid lines that closely encircle the area of interest and, as shown clearly in DeSena's drawings, do not enable the viewing of any anatomical detail of the underlying tissue through the radiographic shadow of the marker.

“The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency.]’ ‘That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.’ Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.” In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (citations omitted) (emphasis in original).

The Examiner has failed to point to any specific teaching or suggestion in DeSena to support his assertion that DeSena's marker is the “same as” Applicant's claimed invention, or otherwise to support his obviousness rejection. Moreover, as explained above, DeSena's clear and unambiguous teaching is to make his markers radiopaque such that any anatomical detail of the underlying tissue necessarily is not visible through the radiographic shadow of the marker. Accordingly, the Examiner's obviousness rejection should be reversed for at least these reasons.

III. CONCLUSION

It is respectfully submitted that the reasons set forth distinguishing the claimed invention from DeSena, coupled with the clear evidence of commercial success, indisputably show that independent claims 20, 36, 46, 55 and 59 are unobvious in view of DeSena. Because claims 21-35, 37-45, 47-53, 54, 56-58, 60 and 61 each depend from, and therefore include all of the limitations of one of these independent claims, it is respectfully submitted that these dependent claims likewise are unobvious over DeSena for the same reasons as the independent claims, and for reciting additional patentable subject matter.

Accordingly, for the foregoing reasons, reversal of the final rejection and allowance of claims 20-61 is warranted and such action is earnestly solicited.

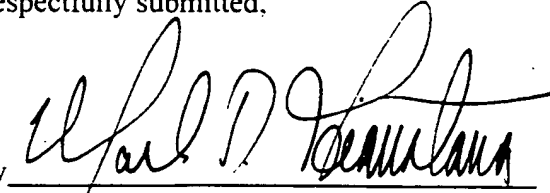
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Respectfully submitted,

August 5, 2002

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